Predicting Participant Consent in mHealth Trials – A Caregiver's Perspective

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Abstract

Informed consent is sought prior to conducting a healthcare intervention on a person. When a healthcare intervention involves a young child, their caregiver is required to provide informed consent on their behalf. However, little is known on the behavioural intentions of participants to provide consent when a mobile health (mHealth) intervention is involved in a clinical trial scenario. Understanding this phenomenon is important, without consent appropriate data may not be collected to empirically examine the implications of mHealth initiatives when delivering healthcare services to children in a 'real world context'. The objective of this paper is to explore the behavioural intentions of caregivers to provide consent for children (under five years of age) to participate in mHealth Randomised Control Trials (RCT) in developing countries and subsequently develop a predictive model for consent giving. Data was captured vis-à-vis interviews with Malawian caregivers in Africa. The findings reveal that emotional response stimuli play a major role during the participant informed consent process resulting in the involvement (or not) of a child within an RCT. The study contributes to, and opens up, avenues for critical research on the role of informed consent as part of RCT-related projects, especially concerning the involvement of children. This new knowledge may be leveraged to address participant uncertainties and subsequently improve the rate of paediatric recruitment in mHealth trial scenarios.

Keywords: Emotional Response Stimuli; Rational Decision Making; mHealth; Consent; Developing Countries

1 Introduction

mHealth refers to the application of mobile information and communication technologies within the healthcare domain to support the delivery of healthcare services (Lester, Ritvo et al. 2010) and represents a shift in focus from traditional paper-based to digitised approaches to delivering healthcare services in an effort to improve the nature of care delivery (Gianchandani 2011). In developing countries mHealth initiatives range from disease surveillance and control (e.g. Malaria, HIV/AIDS, and diabetes), emergency response systems, human resource coordination, management and supervision, mobile-learning to health services monitoring and reporting (Mechael 2006; Varshney 2014). The increase of mHealth initiatives in

developing countries may be attributable to the recent phenomenon of 'Information and Communication Technology for Development' (ICT4D or ICT4Dev) which seeks to generate sustainable development among developing countries through the effective utilisation of ICT (Unwin 2009). The overall objective of ICT4D is to foster economic and socio-economic growth in marginalised communities across the world (Heeks 2008; Unwin 2009). To complement ICT4D, global initiatives in the form of Millennium Development Goals (MDG) were proposed at the start of the decade (2005) which stimulated unprecedented efforts to meet the needs of the world's poorest (i.e. focusing on issues of poverty, hunger, education, gender equality, child mortality, maternal health and environmental sustainability to name but a few). As the deadline for achieving MDG drew to an end (year: 2015) governments worldwide established Sustainable Development Goals (SDG) to build and expand the existing goals to ensure longevity and sustainability of projects in developing countries. SDG commenced in January 2016 which inevitably will see the introduction of more mHealth projects within low and middle income countries, using the statistics of the previous decade as a basis.

To understand mHealth initiatives and their associated implications, pilot studies are often performed prior to the deployment of the solution in routine clinical practice. While existing mHealth studies based around pilot projects have provided rich insights, it is argued that a more rigorous approach (i.e. a comparative study under control conditions) is required to fully appreciate if an intervention (i.e. mHealth application) is successful or not (Cole-Lewis and Kershaw 2010; Mechael 2010). Such an approach is referred to as a Randomised Control Trial (RCT) and requires approval from participants before proceeding with the study. While the implementation of mHealth initiatives is relatively well understood, evidence of behavioural intentions towards consenting to participating in RCTs is less clear. Understanding this phenomenon is important as without consent, appropriate data may not be collected to empirically examine the implications of mHealth initiatives when delivering healthcare services to patients in a 'real world context'. More specifically, the motivation to study RCTs and the informed consent process particularly in developing countries is underpinned by the fact that introducing mobile technology in a clinical domain within low and middle income countries is contextually different from implementation initiatives in the developed world (Walsham and Sahay 2006; Avgerou 2008). Contextual factors reflect dynamic external forces constituted in the user groups' social, cultural, economic, political, technological and institutional environment and, as such, comprise the environment or conditions for decision making tasks (Edwards and Steins 1999). Such factors could potentially influence the informed consent process for approving child participant in a mHealth intervention within a clinical domain. Moreover, Nabulsi, Khalil & Makhoul (2010 p.420) argues that studies exploring parental perceptions in paediatric trials have been primarily investigated in developed countries with few studies investigating "similar parental experiences from non-industrialised countries, where clinical research faces economic, cultural and practical obstacles". The next section explores the notion of research trials.

1.1 Randomised Control Trial: Definition and Characteristics

A Randomised Control Trial (RCT) is often conducted when an intervention project matures and its efficacy needs to be empirically established (Nilsen, Kumar et al. 2012). Simply, an RCT is performed to examine whether an intervention works. Embracing this methodological evaluation requires the (1) use of a control condition to which the experimental intervention is compared; and (2) random assignment of participants to conditions (cf. Gamble, Haley et al. 2014).

In the Information Systems (IS) field pilot/feasibility studies are often performed to explore the feasibility of technological artefacts. However, when used in conjunction with clinical studies pilot/feasibility studies are considered "preliminary studies conducted specifically for the purposes of establishing whether or not a full trial will be feasible to conduct, and that all the necessary components of a trial will work together" (Abbott 2014 p.555). RCTs aim to investigate the effectiveness or efficacy of a healthcare intervention whereas preliminary studies (i.e. feasibility and pilot) aim to determine and to assess, respectively, the intervention

under examination. Thus, feasibility and pilot studies are very practical and descriptive in nature (Lancaster, Dodd et al. 2004) and used to underpin RCTs. The predominant distinction between the three study types lies with the aim of the study. Table 1 summarises the work of Abbott (Abbott 2014) who distinguishes between feasibility, pilot and RCT studies.

Study Type	Objective	Sample Activities Explored
Feasibility Study	To *determine* whether or not it will be feasible to conduct an RCT of a particular intervention in a particular setting.	Willingness of clinicians to recruit participants, response rates to questionnaires, and loss to follow-up.
Pilot Study	To *assess* the key processes necessary for conducting the proposed main RCT.	Processes for assessing eligibility, conducting baseline assessments, randomization procedures, treatment fidelity, and follow-up assessment.
RCT	To *investigate* the efficacy or effectiveness of an intervention(s) compared with a comparison group.	The null hypothesis that intervention A is not more effective than a comparison (typically either a control group or another intervention), in the case of a superiority trial.

Table 1. Distinguishing between feasibility, pilot and RCT studies (Source: (Abbott 2014))

It is important to recognise that different classifications of RCTs exist: namely, parallel-group, crossover, cluster and factorial (Hopewell, Dutton et al. 2010). Each classification is briefly described in Table 1. Notably, this list is not exhaustive and the authors acknowledge that additional classifications exist outside of the most commonly used classifications identified in Table 2.

RCT Classification	Description
Parallel-Group	Each participant is randomly assigned to a group, and all the participants in the group receive (or do not receive) an intervention.
Cross-Over	Over time, each participant receives (or does not receive) an intervention in a random sequence.
Cluster	Pre-existing groups of participants are randomly selected to receive (or not receive) an intervention.
Factorial	Participants are randomly assigned to individual interventions or a combination of interventions.

Table 2. Description of RCT Classifications (Source: Gamble, Haley et al. 2014)

The classification criterion for an RCT is dependent upon the research objective of the study. While RCTs are primarily part of an epidemiological research tradition (Richards and Hamers 2009) their importance when investigating mHealth diagnostic tools is becoming widely recognised (Chib 2013; Davis 2014). One example of a study employing RCTs to examine the efficacy of mHealth include Watts et al., (2013) who conducted a RCT comparing the delivery modality (mobile phone/tablet or fixed computer) of a cognitive behavioural therapy intervention for the treatment of depression. Other examples based in developing countries can be found in the work of Chang et al., (2011), Hoffman et al., (2010), Jones et al.,(2012), Lester et al.,(2010); Mbuagbaw et al.,(2012), Pop-Eleches et al., (2011), & Zurovac et al., (2011).

1.2 Behavioural Intention Research

Behavioural intention research is well documented in the IS field. Common theories applied to exploring behavioural intentions include the Theory of Reasoned Action (Fishbein and Ajzen 1975), Theory of Planned Behaviour (Ajzen 1991) and Technology Acceptance Model (Davis 1989). Behavioural intention is a predictor of future behaviour (Ajzen 1991). The majority of behavioural intention research focuses on the individual who participates in the research initiative themselves. However in paediatric trials/research, consent is obtained by proxy from the child's parent(s) or guardian(s) (referred herein as caregiver) (Peart 2000). It is argued (Caldwell, Murphy et al. 2004 p.805) that caregivers "are uncomfortable with this referred responsibility because of concerns about unknown or unexpected future side-effects and the possibility that the treatment their child receives might later be discovered to be ineffective or even harmful." As a result, emotions and rational decision making are important factors when providing consent on the behalf of another individual for which one is responsible for. Yet, a dearth of research focuses on child participation in studies from the caregivers' perspective when technological artefacts are involved (Carvalho and Costa 2013). To add to this complexity RCTs have certain characteristics which differentiate them from mainstream feasibility or pilot studies (see Table 1). These characteristics have gone unexplored as part of behavioural intention research in the IS domain to date. Building from this, the objective of this paper is to explore behavioural intentions of caregivers to provide consent for children to participate in mHealth RCTs in developing countries and subsequently develop a predictive model for the provision of informed consent.

The remainder of this paper is structured as follows: The theoretical grounding to this study is first discussed focusing on emotional response stimuli and rational decision making. The methodology employed for the study is subsequently outlined. The findings are revealed resulting in the development of a conceptual model. The findings are then discussed in relation to extant literature and the implications of this study to both theory and practice.

2 Theoretical Grounding

Vast amounts of research have been conducted on the topic of emotions versus reasons (i.e. rational decision making) in different scientific fields since the early 1990s (e.g. Macmurray (Macmurray 1937; Simon 1959; Sousa 1979; Toda 1980). The author(s) acknowledge that an association exists, and is well documented in literature, between emotions, rational decision making and behavioural intentions. The aim of this research is not to reinvent the wheel in this domain but instead to embrace such classical perspectives to enhance current understanding surrounding a relatively new phenomenon, namely the behavioural intentions of caregivers to provide consent for children to participate in mHealth trial scenarios. The decomposition of the broad constructs of emotional response stimuli and rational decision making provides a more holistic view of the consent process from a caregiver's perspective within a healthcare context.

Healthcare is very much a personalised experience (Rigby, Roberts et al. 2000) which represents a markedly different social and technical context compared with many of the industries (e.g. finance and manufacturing) where research is conducted (Chiasson and Davidson 2004). Healthcare consists of an extraordinarily diverse set of activities (Lyons, Woloshynowych et al. 2005) with a strong consumer focused perspective (Kay 2007). Additionally, Finnell et al., (2003) argues that in an electronic Health (eHealth) environment data is considered at the level of the community, rather than solely on an institutional basis. These views, aligned with the fact that mHealth technologies in developing countries are relatively new, provide a novel perspective in the area of emotions and reasoning.

Building on this, the following sections describe emotional response stimuli and rational decision making in the context of caregivers intending to provide (or not) consent for children to participate in mHealth trial scenarios.

2.1 Emotional Response Stimuli

Emotion is defined as a mental/cognitive reaction that transpires when individuals encounter significant relationships with others or with their environment (Barrett and Campos 1987). That is, emotions are "subjectively experienced state that can be described qualitatively and is accompanied by changes in feeling, physiology, and expression" (Adam, Gamer et al. 2011 p.4). This paper focuses on the stimuli which give rise to emotional responses in RCT scenarios. More specifically, the authors concentrate on this approach to gain a rich understanding of the objects or events which can cause an emotional response (Adam, Gamer et al. 2011). Applying this approach, referred herein as 'emotional response stimuli', often incorporates a conscious, cognitive appraisal of the stimulus/stimuli by the individual in certain circumstances. In the context of this research, RCT emotional response stimuli refer to parallel-group (see Table 1 for description) RCT based stimulus/stimuli which could potentially be encountered by participants during the clinical trial. Researchers have long advocated the importance by which emotional responses play in an individual's decision making process (e.g. Angie, Connelly, Waples & Kligyt (2011); Lerner & Keltner (2000); Paulus & Yu (2012); Sanfey (2007); Schwarz (2000)).

In 2015, the United Nations Children's Fund (UNICEF), World Health Organisation (WHO), World Bank, United Nations Department of Economic and Social Affair (UN DESA) Population Division recently reported 5.9 million children died worldwide before the age of 5 years (UNICEF 2015). That is a staggering 16,000 children who die on a daily basis due to preventable or treatable diseases. Without doubt, the death of a child of any age is a profound, difficult, and painful experience. Emotions can therefore have an impact on caregivers' decision making.

Emotions either play a facilitating or hindering role in the decision-making process (De Guinea and Markus 2009; Li, Ashkanasy et al. 2014). For instance, Chown, Jones & Henninger (2002 p.352) argue that "emotions are often seen as being disruptive to rational thought". This viewpoint is also expressed by other theorists such as Ashton-James & Ashkanasy (2008) and Lerner & Tiedens (2006). Conversely, Damasio (Damasio 1994; Damasio 1998) has shown that emotions can improve an individual's decision-making process. Further, it is argued that emotions play an integral role in the decision-making process (Tyszka and Zaleskiewicz 2012; Li, Ashkanasy et al. 2014). Building from this, if caregivers in developing countries perceive that involving their child(ren) in RCT studies will increase their livelihoods and chance of survival then the likelihood of participant consent increases (Jansen-van der Weide, Caldwell et al. 2015). Yet, if they perceive that involvement will put their child(ren) at risk then the chance of caregivers' providing consent is reduced (Jansen-van der Weide, Caldwell et al. 2015).

2.2 Rational Decision Making

Decision making is "a process of identifying a problem, evaluating alternatives, and selecting one alternative" (Cole 2004 p.151). One traditional approach to understanding individual decision making is based upon Edwards' Classical Decision Theory (Edwards 1954). This theory focuses on instrumental rationality which employs a strategy by seeking the best possible alternative to maximise the achievement of goals and objectives. This implies that a clear set of alternate choices can be generated and their likely outcomes can be predicted with a significant degree of confidence. Additional approaches are proposed (March 1958; Tversky and Kahneman 1974; Mintzberg, Raisinghani et al. 1976; Simon 1979) which attempt to understand individual decision making. Although the approach to understanding decision making varies in literature there appears to be widespread consensus that decision making often occurs under three conditions: certainty (outcomes of actions are certain), risk (outcomes are not certain but their probabilities are known, as in some games of chance), and uncertainty (probabilities of outcomes are unknown) (Simon 1959). These are utilised to bring greater clarity to the decision making process.

Further to this, rational decision-making involves choosing between available alternatives so as to maximise ensuing benefits (Simon 1979). That is, a good decision is perceived as having high outcome benefits (it is worthwhile) and low outcome costs (it is worth it). By this criterion, "utility maximisation could be seen as a rational decision-making model that follows shared and accepted rules of decision-making (Li, Ashkanasy et al. 2014 p.294)". Bearing this in mind we consider the case of Malawi, Africa. Malawi is ranked as one of the ten poorest countries in the world with a high rate of child mortality and morbidity (Callaghan-Koru, Gilroy et al. 2013). Therefore, Malawians may perceive that the advantages (e.g. improved healthcare services with a focus on reducing child mortality and morbidity) of participating in RCT based studies may out-weigh the disadvantages (remaining with the status quo healthcare system).

Figure 1 represents a diagrammatic model of the association between emotional response stimuli, rational decision making and behavioural intentions. As part of our study, we set out to decompose this model to enhance our understanding of caregivers' consenting their child(ren) in paediatric RCTs in developing countries.

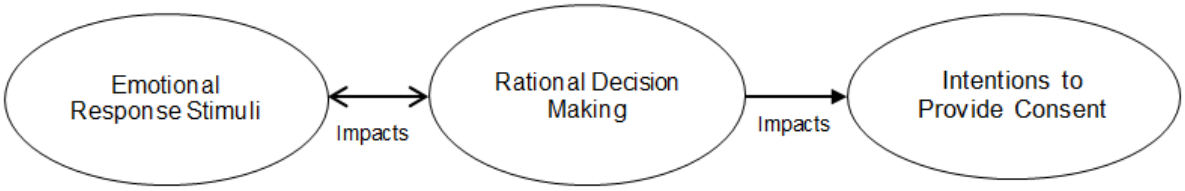

Figure 1. Emotional Response Stimuli and Rationale Decision Making Model of Caregivers' Behavioural Intentions to Provide Consent for Children to participate in mHealth Randomised Control Trials

The following section describes the methodology employed by the researchers to explore this model. Based on the results, a conceptual model is proposed before the implications of this research conclude this paper.

3 Methodology

This research explores the behavioural intentions of caregivers to provide consent for children to participate in mHealth randomised control trials in developing countries and subsequently develop a predictive model for consent giving. A case study approach (i.e. Mzuzu, northern Malawi) was employed by the researchers as this facilitates an in-depth understanding of the phenomenon and its context (Yin 1994; Cavaye 1996). Considered one of the most important sources of information in qualitative research (Yin 1994; Stake 1995) interviews were conducted for collecting data in an effort to describe the meanings of central themes in the world of study (Kvale 1996). As a result, a qualitative case study approach was deemed appropriate to yield data regarding caregivers' feelings about the process used to allocate their child(ren) to RCTs.

Ethical approval was granted by the Social Research Ethics Committee (SREC) within University College Cork, Ireland. Each caregiver was provided with a description of the research prior to seeking informed consent. This description was made readily available in English or Tambuku (local dialect) by members of an NGO (Ungweru) who conduct community based activities in the local region. Each caregiver was also provided with an informed consent form indicating that the purpose and nature of the study had been explained to the participant (i.e. caregiver); they were participating voluntarily; they understood that they could withdraw from the study, without repercussions, at any time, whether before it starts or while they were participating; they understood that anonymity would be ensured in the write-up by disguising any identity. Once the caregivers understood the study and were willing to participate in it informed consent was obtained from the participant vis-à-vis a signature and date.

Working closely with Community Health Workers (CHWs) in the community, ten households were identified which had sick children under the age of five who previously attended a clinic

in the community of Dunduzu and Doroba in Mzimba North, Malawi, Africa. In their study of two African countries, Guest, Bunce & Johnson (2006) undertook a detailed data analysis of the transcript coding process of sixty interviewees. The results of this study showed that 92 percent of codes identified for the entire sample were found in the early stage of data analysis amongst the first twelve interviews (Guest, Bunce et al. 2006). For this study, ten interviews with female caregivers were performed in collaboration with our African partners using a purposive sampling approach (Patton 1980). Like Guest et al., (2006), this study included a comparatively homogenous population and had a focused objective. These factors are important in order for theoretical saturation to be achieved in a study such as this (Eisenhardt 1989; Guest, Bunce et al. 2006). Interviews were conducted in the local dialect of Tambuku in the caregivers' homes. Each participant was given a standardised briefing prior to the interview about RCTs and what they entail.

The data was analysed using open, axial and selective coding as advocated by Strauss & Corbin (Strauss and Corbin 1990). The rationale for employing their techniques is that it is favourable for a research study engaged in advancing current understanding engaged in theory building. Moreover, these content analysis techniques can be utilised in the absence of, or in conjunction with existing theory (Strauss and Corbin 1990; Urquhart 2001). Operationalising this content analysis approach required the researchers to first examine the data 'word-by-word'/'line-by-line' to ascertain the main ideas (open coding). Through comparative analysis across interviews and with regards to similarities and differences, the researchers then grouped codes together and formed, where applicable, more abstract categories or themes. The next step examined the data to establish if relationships between categories and other (sub) categories exist (axial coding). Finally, selective coding was undertaken to identify the relationships between categories using hypothesised conditions, context, strategies and consequences.

4 Findings

This section presents the findings of this study and discusses its implications for the a priori model (Figure 1). Findings enable the researchers to refine the conceptual model derived from existing literature, more specifically in terms of emotional response stimuli and rational decision making. As a result, a revised model is developed and presented (Figure 2).

4.1 Overview of Interviewees

Table 3 provides an overview of the interviewees' demographics. Data was gathered during October 2014 and all interviews were transcribed into English for analysis.

Question	Overview
Age	50% (n=5) between 18-28 years
	50% (n=5) between 29-39 years
Level of Education	10% (n=1) Junior Primary
	30% (n=3) Senior Primary
	20% (n=2) Junior Certificate of Education
	40% (n=4) Malawi School Certificate of Education

Table 3. Overview of Interviewees' Demographics

4.2 Emotional Response Stimuli

In this paper, the authors identified a number of RCT based emotional response stimuli which have an impact on caregivers rational decision making when intending to provide consent for

a child to participate in mHealth RCT. These include (1) perceptions of RCTs involving children, (2) perceptions of chance allocation, (3) perceptions of experimentation, (4) perceived (mis)trust of mobile technology and (5) perceived novelty.

The first stimulus which triggers emotional responses is that of '***Perceptions of RCTs involving children'***. Interviewees' perceived that clinical research involving children was a positive initiative. This is exemplified in a comment from one caregiver who stated "its [clinical research that involves children less than five years of age] a wonderful area to explore because children by themselves fail to communicate effectively the signs and symptoms of what they suffer from" (Caregiver 1). This viewpoint is similarly expressed by another caregiver stating "children don't express properly what they suffer from. I feel it will help to find an efficient way of helping out children" (Caregiver 3).

The second stimulus to elicit emotional responses from caregivers was that of '***Perceptions of Chance Allocation'***. As outlined earlier (Section 1.1), RCTs often require the use of a control condition to which the experimental intervention is compared and a random assignment of participants to conditions (note: For the purpose of this research, the control condition would involve using the existing paper-based approach to delivering healthcare services to children less than five years of age). The findings reveal that the perception of chance allocation did not have a significant influence on their decision making process providing the correct diagnosis and treatment were received by the sick child. This is reflected in the following comments; "I want help for my sick child. Both approaches [paper based or mobile] will help our sick children. I don't see any issue using this arrangement" (Caregiver 3); "I feel there is no problem because both approaches help the children" (Caregiver 6); and "to use both approaches is ok with me, because the approaches work to help our children. What I want is to get my child treated regardless of the approach used" (Caregiver 9). Interestingly, one care-giver (number 5) stated that this controlled approach was beneficial as "it's an opportunity to compare the performance of the two approaches." In some situations however, caregivers perceived that this element of chance would only cause confusion in the community. This is reflected in the following comment such as "I feel they should use one approach, with paper-based or mobile technology to avoid confusing the community" (Caregiver 7).

The third stimulus, '***Perceptions of Experimentation'***, also triggered some emotional responses from the caregivers interviewed in this study. It is during an RCT that the efficacy of mHealth needs to be empirically established thus, there remains an element of 'trial and error'. The findings reveal that caregivers do not fear the experimentation element associated with the technological artefact provided that the CHWs (end users of the mHealth during the RCT) continue to rely on their tacit knowledge and experience. That is, they have control over the technology during the trial. This is exemplified in the following comments; "The community health workers have been diagnosing and treating my children all along in this village. They will use the mobile technology, so I feel they will have control" (Caregiver 2) and "It will be controlled by trained and experienced community health workers" (Caregiver 3).

The fourth stimulus is closely related to the previous stimulus and includes '***(Mis)Trust of the technology***'. Perceptions of the trustworthiness of the mHealth technology varied across caregivers. For instance comments ranged from "I trust the technology because I have been told that mobile technology works the same way as the paper-based approach" (Caregiver 4), "It's a new technology. I will trust it" (Caregiver 5), "If the community health workers will operate it, I will trust it" (Caregiver 6) and "I believe the mobile technology is like any other technologies in big hospitals to diagnose different diseases. Based on that, I will trust the mobile technology" (Caregiver 9). Conversely, one caregiver doubted the technology stating that "I do not trust the technology because I am not sure about its performance" (Caregiver 10). Another caregiver would only trust the technology providing that the output would confirm what the caregiver already was aware of: "Before I go to the clinic for diagnosis and treatment of my child I will have the knowledge and behaviour of the child. If the mobile technology will confirm what I had observed at home, then I will trust the mobile technology" (Caregiver 1).

The fifth and final stimulus to trigger emotional responses from the caregivers is '***Perceived Novelty***'. The caregivers interviewed in this study had little to no experience with smartphone devices so introducing such an innovation into their community was perceived as an exciting initiative. The perceived novelty of the technology was found not to discourage caregivers from providing consent but in fact welcomed the initiative. For example, "I welcome the idea of clinical research which uses mobile technology because that is the way to go these days. The world has become technological" (Caregiver 7) and "I've not seen the mobile technology before. I look forward to seeing it being tested here" (Caregiver 9). While the perceived novelty was not seen as an obstacle for the majority of caregivers, there was one caregiver who expressed his/her concerns with the technology stating "I've doubts about its functionality" (Caregiver 10).

The findings presented in this section demonstrate that perceptions of RCTs involving children, chance allocation, experimentation, (mis)trust of mobile technology and novelty are emotional response stimuli often encountered by caregivers in an mHealth trial scenario. The following section now focuses on rational decision making.

4.3 Rational Decision Making

Existing studies argue that rational decision making can impact the behavioural intentions of individuals. For this study, two rational decision making concepts were identified. These include (1) perceived net benefits and (2) perceived uncertainty costs.

First, the '***Perceived Net Benefits***' associated with the mHealth RCT include improved diagnosis and treatment of a sick child, improved delivery of effective and efficient healthcare services at the point-of-care and improved accuracy in terms of maintaining the medical records of a sick child. These perceived net benefits were reported by all caregivers with comments such as "one of the advantages is that my child will get the right diagnosis and right treatment" (stated by Caregiver 1 but similarly expressed by Caregivers 2,3,5,6 and 9). Improved effective and efficient services were reflected in comments such as "my child will get a transparent assessment" (Caregiver 4) and "My opinion is that this is an efficient way of patient assessment" (Caregiver 8). Caregiver 5 expressed that "the community health workers will greatly benefits as much as the community" which depicts the societal wide perceived net benefits associated with mHealth RCT initiatives. The most important perceived net benefit was reflected in a comment from Caregiver 10 who stated that "the idea is to help children to have a healthy life."

The second rational decision making concept identified in this paper is that of '***Perceived Uncertainty Costs***'. Essentially an RCT is performed to examine whether an intervention works thus, there is an element of uncertainty associated with the mHealth intervention. This uncertainty is reflected in various comments from caregivers such as "I feel it is a risk because I don't know perfectly well how it will work on our children here" (Caregiver 2) and "It has a risk" (Caregiver 8). Caregiver 10 reveals that the status quo of using the paper-based approach is precise when delivering healthcare services to children as "it's been tested".

The findings presented in this section demonstrate that perceptions of net benefits and uncertainty are also encountered by caregivers in a trial scenario. Overall, the findings revealed that emotional response stimuli affect rational decision making. This is exemplified in Table 4. The chain of evidence vis-à-vis Beaudry & Pinsonneault (2005) presented in Table 4 acts to underpin the proposition that emotional response stimuli influences rational decision making.

Relationship	Evidence
Perceptions of RCTs involving children > Net Benefits and Uncertainty Costs	"I feel the clinical research will help ways that will enable our children to grow healthy. I also see it as a challenge because I'm not really sure to what extent children will be directly involved" (Caregiver 4). "My child will set an example to others about the importance of participating in clinical research for the good of others" (Caregiver 5). "I want my child to get diagnosed and get the right treatment… I (my child) look forward to participating in clinical research despite the fact that I'm not sure about its functionality" (Caregiver 6).
Perceptions of Chance Allocation > Net Benefits and Uncertainty Costs	"I prefer mobile technology because the paper based might have a higher risk of making a wrong diagnosis and treatment" (Caregiver 1). "I prefer the mobile technology because I feel the mobile technology will be more accurate than paper based approach in diagnosis and treatment" (Caregiver 4).
Perceptions of Experimentation > Net Benefits and Uncertainty Costs	"Because the mobile technology will work just as the paper based, then I don't have any problem. However, I would like that the mobile technology be tested first" (Caregiver 1). "My child will set an example to others about the importance of participating in clinical research for the good of others" (Caregiver 5).
(Mis)Trust of Technology > Net Benefits and Uncertainty Costs	"It will be difficult in the first place to completely trust the clinical research that uses mobile technology but I fell it will provide better and efficient health services to children" (Caregiver 2). "While I'm happy that my child may be exposed to clinical research using mobile technology, I still need convincing that it will work perfectly well" (Caregiver 4).
Perceived Novelty> Net Benefits and Uncertainty Costs	"It will be completely new and strange. It will be a challenge to understand it when they are used at the clinic" (Caregiver 3). "I agree that I have not seen it before. However, I fell this clinical research is important for the good health of our children" (Caregiver 9).

Table 4. Evidence of Emotional Response Stimuli influencing Rational Decision Making

4.4 Outcome: Intentions to Provide Consent for Children to participate in mHealth RCT

From the ten caregivers interviewed, only one caregiver would refuse to give consent for their child(ren) to participate in mHealth RCT studies. The key concerns stemmed from the emotional responses experienced by the caregiver, primarily surrounding 'fear of experimentation', 'mistrust of technology' and 'inclusion of children in clinical trials'. This caregiver in this situation perceived that the advantages of participating did not outweigh the disadvantages. Yet, despite this one caregiver refraining to provide consent, the remaining caregivers intend to provide consent for their child (ren) to participate in mHealth RCT studies if asked. The findings reveal that emotional response stimuli primarily facilitated rational decision making however, there were instances whereby emotional response stimuli would hinder rational decision making. Based on the findings presented a decomposed conceptual model (Figure 2) is illustrated for future empirical testing and validation.

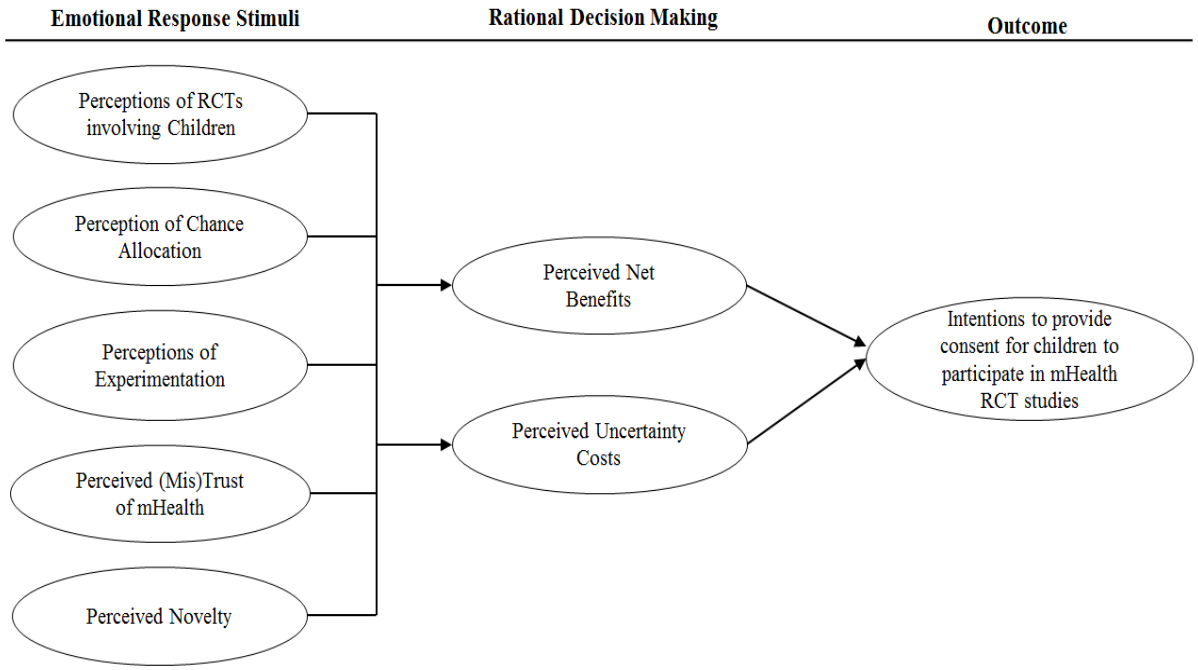

Figure 2. Predictive Conceptual Model of Caregivers' Behavioural Intentions to Provide Consent for Children to Participate in mHealth Randomised Control Trials

With any initiative, identifying the pros and cons to a project may assist in an individual's decision making process. While our findings support this argument it was also identified that emotional response stimuli can influence how a project is perceived in terms of advantages and disadvantages. This new conceptual model (Figure 2) portrays these associations.

5 Discussion

The impact of emotional response stimuli and rational decision making on caregivers' behavioural intentions to provide consent for children to participate in mHealth RCT has gone relatively unnoticed in existing literature. From synthesising the literature a preliminary model is initially proposed, which is further refined vis-à-vis a case study of caregivers in Mzimba North, Malawi Africa. The findings presented in this paper corroborate decision making research which has found that emotional response stimuli can both hinder (Caldwell, Butow et al. 2003) and facilitate (Zupancic, Gillie et al. 1997) rational decision making thus, ultimately impacting whether or not caregivers consent their children to participate in mHealth RCT studies in developing countries. The findings identified five emotional response stimuli associated with mHealth RCT characteristics including (1) perceptions of RCTs involving children, (2) Perceptions of chance allocation, (3) perceptions of experimentation, (4) perceived (mis)trust of mobile technology and (5) perceived novelty. Two rational decision making concepts were also identified influencing the behavioural intentions of caregivers to provide consent on behalf of their children to participate in mHealth RCT (1) perceived net benefits and (2) perceived uncertainty costs. Figure 3 depicts the recommendations which will be further outlined.

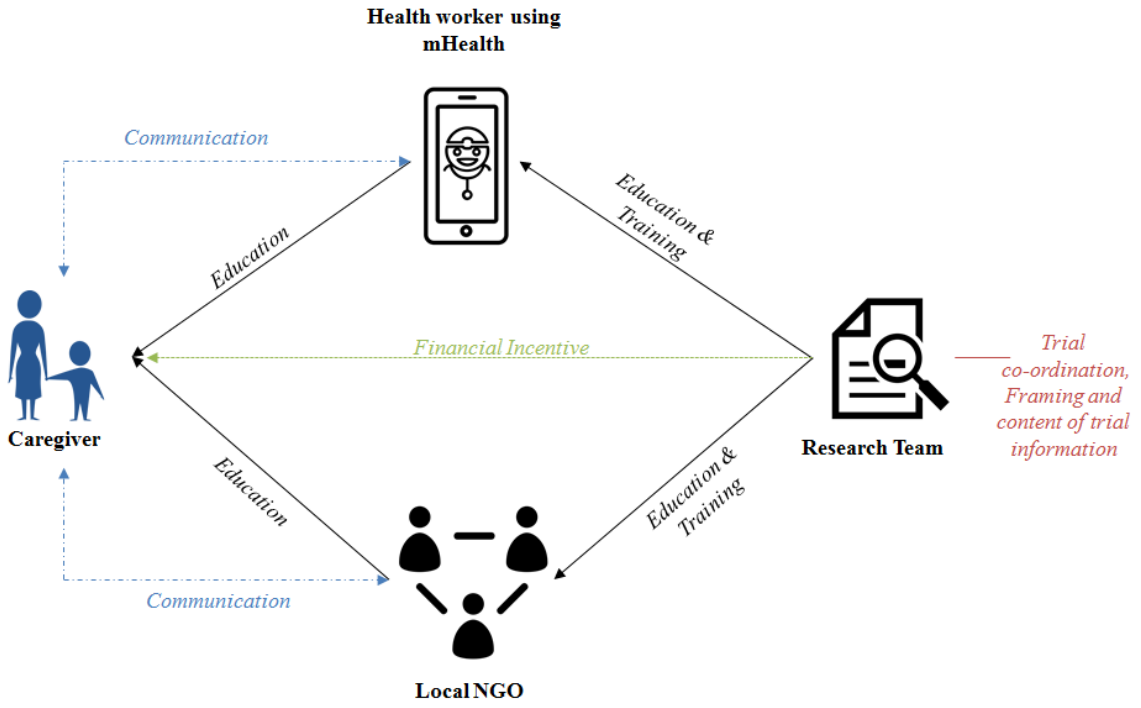

Figure 3. Improving Child Recruitment in mHealth Clinical Trials

Perceptions of RCTs involving children increases caregivers' vulnerability and contradictory feelings about the trial as the caregiver is not directly receiving diagnosis/treatment based on the output from the mHealth technology. Similarly, Caldwell et al., (2004) identified that caregivers were more willing to provide consent for their own participation in trails than assenting their child(ren). Caregivers' fear of harm or adverse events which potentially could be faced by the child is further enhanced through their perceptions of experimentation. Often parental misconceptions about the research process such as the meaning of randomisation and perceived risks associated with the intervention (i.e. mHealth technology) influences their decision (Nabulsi, Khalil et al. 2010). Yet, caregivers' perceive that the benefits for their child(ren) participating in mHealth RCTS outweighs the risks involved. A possible reason for this may be attributable to the contextual environment caregivers' are situated in. The current delivery of healthcare services in Malawi, Africa is quite fragmented, with insufficient resources and suffers from a brain drain of highly skilled workers (Coloma and Harris 2009) which leaves a shortage of well-educated professionals. Research using mHealth technologies in trial scenarios involving children found that caregivers perceived that community health workers using mHealth technologies provided (a) a more thorough examination of their child and (b) were more knowledgeable as a result (Mitchell, Getchell et al. 2012). In the work of Mitchell et al., (2012), caregivers had never seen or interacted with the mHealth technology. Therefore, the perceived novelty of the technological artefact isn't seen as an inhibitor but more a facilitator in the consent process.

Based on these results recruitment to trials in developing countries in terms of the consent giving process can be improved by considering the contextual nature in which mHealth interventions are being introduced. The critical component is providing education to the caregiver surrounding the intervention itself (i.e. mHealth technology and how it will be used in the trial). Given the important role that Non-Governmental Organisations (NGOs) play in developing countries, research teams should corroborate with local NGOs in the area for which the trial is envisioned to take place as NGOs currently provide information to communities in developing countries on various initiatives. Individuals within NGOs should be educated on the trial protocol. It is also clinically imperative that the community health workers are educated on the trial and more specifically receive training to ensure that they can utilise the

mHealth technology according to trial protocol. To ensure that both community health workers and NGOs are sufficiently educated the research team must have the trial coordination activities clearly articulated and trial information documented prior to commencing the trial. Trial information should explicitly detail how the mHealth intervention will be used during the trial and what the implications are for the child involved (i.e. individual and community-wide benefits and risks). This information, supplemented with additional information around mobile technology and healthcare, should be relayed in a clear, concise manner by the NGO to caregivers prior to the trial to increase awareness around the intervention. Caregivers should also be made aware that participation in mHealth RCTs are on a voluntary basis whereby the caregiver and his/her child are free to leave the study at any stage. To ensure full commitment by caregivers it is imperative that a two-way communication path is implemented between the consent giver and the health workers/local NGOs to facilitate any question and answer sessions. In some situations financial incentives may encourage caregivers to provide consent but no evidence of this was found in this study.

6 Conclusion

The traditional paper-based approach for recording and exchanging clinical data in healthcare environments is progressing towards automation. The arrival of mHealth has created an opportunity to document healthcare information in electronic format at the point-of-care. Recognising the profound benefits that such technological tools can offer many mHealth initiatives have been and will continue to be deployed in developing countries. As healthcare interventions, mHealth technologies are undergoing rigorous efficacy and/or effectiveness trials in resource poor settings. The majority of these interventions target cohorts of children under the age of five years in an effort to address the high mortality rates which exists in such regions of the world. However, in order to conduct such investigations (commonly referred to as Randomised Clinical Trials) requires consent to be given by a caregiver. Yet, a dearth of research exists highlighting the behavioural intentions of caregivers to provide consent for children to participate in trials involving mobile technology (Carvalho and Costa 2013). This paper attempts to close this gap by exploring perceptions of caregivers in Malawi, Africa on the informed consent process, focusing on emotional response stimuli and rational decision making in order to better predict the likelihood of participant consent in studies such as these.

The findings identified five emotional response stimuli and two rational decision making concepts which influence the behavioural intentions of caregivers to provide consent, on behalf of their children, to participate in mHealth RCT. The findings presented in this paper should be considered in the context of the study's limitations. Firstly, this study did not take into account the severity of a child's illness and how this may have an impact on caregivers' behavioural intentions. Secondly, this study focused on caregivers providing (or not) for children specifically under the age of five years. Thirdly, this research solely focused on one classification of RCTs (i.e. parallel-group). Fourth, it is important to note, that an inverse association between emotional stimuli and rational decision making can exist. That is, rational arguments can affect emotional stimuli. For instance, data presented in this paper reveals that 'mistrust of technology affects net benefits and uncertainty costs', but the researchers acknowledge (although no evidence was found in the dataset) the counter argument that net benefits and uncertainty costs affect mistrust.

While the research presented in this paper has emphasised a clear gap in the existing literature and the case study results highlight the influence of emotional response stimuli and rational decision making on the behavioural intentions of caregivers to provide consent for children to participate in mHealth RCT, the authors argue that future research in this area would require a broader spectrum of participants across a number of demographics to provide a richer picture of the findings. More specifically, researchers should examine testable / verifiable elements around the model (i.e. creating hard data) which address the limitations of this study to enhance current understanding in this domain. The model could be further improved by introducing a rating scale of 'very emotional' to 'very rational' to determine if contextual factors

(e.g. age of the child, severity of the disease, etc.) affect the emotional and/or rational responses of caregivers.

Nonetheless, it is imperative to reemphasise that clinical trials involving children are argued to have resulted in significant improvements in the diagnosis and treatment of paediatric healthcare services (Caldwell, Murphy et al. 2004; Molyneux, Mathanga et al. 2012). This study highlights the importance of obtaining informed consent as part of mHealth studies. In doing so, this paper contributes to research and practice by (1) deriving a predictive model of consent giving, (2) identifying the role of emotions and reasoning as part of informed consent and (3) understanding caregivers' perceptions surrounding trial participation, facilitating improved engagements with participants may result in terms of paediatric recruitment. It is essential that caregivers are educated about mHealth RCTs and the opportunities that they afford in terms of potential improvements in the availability, efficiency and effectiveness of health services with the opportunity to improve patient health outcomes in the long term.

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